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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91206212
Party	Defendant entrotech, inc.
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Signature	/Erin M. Hickey/
Date	05/21/2015
Attachments	2015-05-21 Applicant's Notice of Reliance + Exhibits (Internet Materials) 3.pdf(5177103 bytes)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD**

In the matter of application Serial Nos.:

85/499,349 for the mark **CHLORADERM**
85/499,345 for the mark **CHLORABSORB**
85/499,337 for the mark **CHLORABOND**
85/499,332 for the mark **CHLORADRAPE**

Filed on December 19, 2011

Published in the *Official Gazette* on May 29, 2012

CAREFUSION 2200, INC.,

Opposer,

v.

ENTROTECH LIFE SCIENCES, INC.,

Applicant.

Combined Opposition Proceeding No. 91-206,212

United States Patent and Trademark Office
Trademark Trial and Appeal Board
P.O. Box 1451
Alexandria, Virginia 22313-1451

APPLICANT’S NOTICE OF RELIANCE

Pursuant to Rule 704.08(b) of the Trademark Trial and Appeal Board’s Manual of Procedure and 37 C.F.R. § 2.122(e), Applicant Entrotech Life Sciences, Inc. (“Applicant” or “Entrotech”) hereby notifies Opposer CareFusion 2200, Inc. (“Opposer” or “CareFusion”) of its reliance upon the following publicly available Internet materials (identified as Exhibits G1 – G7):

Exh .No.	Document	Title/Description	URL
G1	CareFusion Website – Chloraprep product page	Website printouts showing broad overview of the Chloraprep product	http://www.carefusion.com/medical-products/carefusion-brands/chloraprep/
G2	Drugs.com Chloraprep One-Step	Website printouts showing Chloraprep packaging	http://www.drugs.com/pro/chloraprep-one-step.html
G3	Entrotech Web Page	Website printouts showing Entrotech’s website	http://www.entrotechlifesciences.com/
G4	Entrotech Web Page	Website printouts showing Entrotech’s website	http://www.entrotech.com/solutions/
G5	CareFusion Webpage -- Infection prevention FAQs	Website printouts describing Chloraprep	http://www.carefusion.com/medical-products/infection-prevention/skin-preparation/faq.aspx
G6	CareFusion Webpage -- CareFusion Brands	Website printouts showing all CareFusion brands	http://www.carefusion.com/medical-products/carefusion-brands
G7	CareFusion webpage – Chlorashield product page	Website printouts showing broad overview of the Chlorashield product	http://www.carefusion.com/medical-products/infection-prevention/vascular-dressings/chlorashield-iv-dressing.aspx

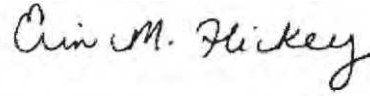
Applicant will rely upon these publicly available Internet materials to establish:

(1) that confusion between Applicant’s CHLORADERM, CHLORABSORB, CHLORABOND, and CHLORADRAPE marks at issue in this Opposition, on the one hand, and Opposer’s CHLORAPREP and CHLORASHIELD marks at issue in this Opposition, on the other hand, is not likely; (2) the dissimilarity of the marks at issue in this Opposition; (3) the dissimilarity of the goods at issue in this Opposition; (4) the dissimilarity of the channels of trade and marketing/advertising at issue in this Opposition; (5) the purchasing conditions and the sophistication of the purchasers of the goods at issue in this Opposition; (6) the weakness of Opposer’s CHLORAPREP and CHLORASHIELD marks; and (7) the scope of Opposer’s use of its CHLORAPREP and CHLORASHIELD marks.

Dated: May 21, 2015

Respectfully submitted,

FISH & RICHARDSON P.C.

A handwritten signature in cursive script that reads "Erin M. Hickey".

By: _____

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Attorneys for Applicant,

ENTROTECH LIFE SCIENCES, INC.

EXHIBIT G1



Overview

- [ChloroPrep® 1 mL applicator](#)
- [ChloroPrep® Sepp® 0.67 mL applicator](#)
- [ChloroPrep® Frepp® 1.5 mL applicator](#)
- [ChloroPrep® 3 mL applicator](#)
- [ChloroPrep® 10.5 mL applicator](#)
- [ChloroPrep® 26 mL applicator](#)
- [ChloroPrep® swabstick](#)

RESOURCES

- [Skin preparation](#)
- [ChloroPrep® FAQs](#)
- [The ChloroPrep® advantage](#)
- [Using ChloroPrep®](#)
- [Why skin preparation matters](#)

DOWNLOADS

- [ChloroPrep material safety data sheet](#)

ChloroPrep®

Use chlorhexidine gluconate and isopropyl alcohol for preoperative skin prep

ChloroPrep® patient preoperative skin preparation is a rapid-acting, persistent and broad-spectrum antiseptic for a wide range of procedures. The 2% chlorhexidine gluconate (CHG) and 70% isopropyl alcohol (IPA) formulation acts fast and keeps fighting bacteria for at least 48 hours.¹

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ChloroPrep® 1 mL applicator

With its unique delivery system, the easy-to-use 1 mL applicator can help promote aseptic techniques and best practices.



ChloroPrep® 3 mL applicator

The ChloroPrep 3 mL applicator is an easy-to-use applicator that provides our CHG/IPA formulation, with a Hi-Lite Orange® tint option.



ChloroPrep® 10.5 mL applicator

Our ChloroPrep 10.5 mL applicator lets you easily apply our unique formulation for skin preparation, available in a clear, Hi-Lite Orange® or Scrub Teal® tint.



ChloroPrep® 26 mL applicator

The ChloroPrep 26 mL applicator helps you easily deliver our CHG/IPA solution, available in a clear, Hi-Lite Orange® or Scrub Teal® tint.



ChloroPrep® Frepp® 1.5 mL applicator

The patented wing design provides more control over releasing the solution while reducing risk of cross-contamination.

ChloroPrep® Sepp® 0.67 mL applicator

The patented design enables you to easily activate the applicator, which flows solution into the sponge tip for you to gently apply.

Get Informed

[Our Brands](#)
[Our Catalogs](#)



Chloraprep® swabstick

This swabstick prepares patient skin for surgery—just tear open the pouch, twist and remove the swabstick, and apply the foam tip to the patient.

References

- 1 Denton, Graham. "Chlorhexidine." In: Block, S., editor. *Disinfection, Sterilization and Preservation, 5th Edition*. Philadelphia: Lippincott, Williams & Wilkins, 2001, 321–336.

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EXHIBIT G2



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Chloraprep One-Step

Generic Name: [chlorhexidine gluconate](#) and isopropyl alcohol

Dosage Form: [solution](#)

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Side Effects

Dosage

Professional

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ChloraPrep® Frepp® Drug Facts

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Active ingredient

Chlorhexidine gluconate 2% w/v

Isopropyl alcohol 70% v/v

Purpose

Antiseptic

Uses

Use for the preparation of the patient's skin prior to surgery.

Official Site

VESIcare® (solifenacin succinate) Find Important Product Information



Warnings

For external use only. Flammable, keep away from fire or flame. To reduce risk of fire, PREP CAREFULLY:

solution contains alcohol and gives off **flammable vapors**
do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair).

avoid getting solution into hairy areas. **Wet hair is flammable.** Hair may take up to 1 hour to dry.

do not allow solution to pool

remove wet materials from prep area

Do not use

in children less than 2 months of age because of the potential for excessive skin irritation and increased drug absorption

on patients with known allergies to chlorhexidine gluconate or isopropyl alcohol

for lumbar puncture or in contact with the meninges

on open skin wounds or as a general skin cleanser

When using this product

Slideshow: Debunking The Myths - HIV/Aids Unravelled



keep out of eyes, ears, and mouth. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a doctor.

Stop use and ask a doctor if

irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

to reduce the risk of fire the following ☑ strategies are recommended:

use in a well ventilated area

avoid getting solution into hairy areas. Wet hair is flammable. Hair may take up to 1 hour to dry.

do not allow solution to pool

tuck prep towels to absorb solution, and then remove

remove wet material from prep area

maximal treatment area for one applicator is approximately 2.5 in. x 2.5 in. (42 cm²). Discard the applicator after a single use.

pinch the wings on the applicator to break the ampule and release the antiseptic. Do not touch sponge.

Wet the sponge by repeatedly pressing and releasing the sponge against the treatment area until liquid is visible on the skin.

dry surgical sites (such as abdomen or arm): Use repeated back-and-forth strokes of the applicator for approximately 30 seconds. Completely wet the treatment area with antiseptic. Allow the area to air dry for approximately **30 seconds**. Do not blot or wipe away.

moist surgical sites (such as the inguinal fold): Use repeated back-and-forth strokes of the applicator for approximately 2 minutes. Completely wet the treatment area with antiseptic. Allow the area to air dry for approximately **one (1) minute**. Do not blot or wipe away.

Other information

store between 15-30 °C (59-86 °F)

avoid freezing and excessive heat above 40 °C (104 °F)

Inactive ingredients

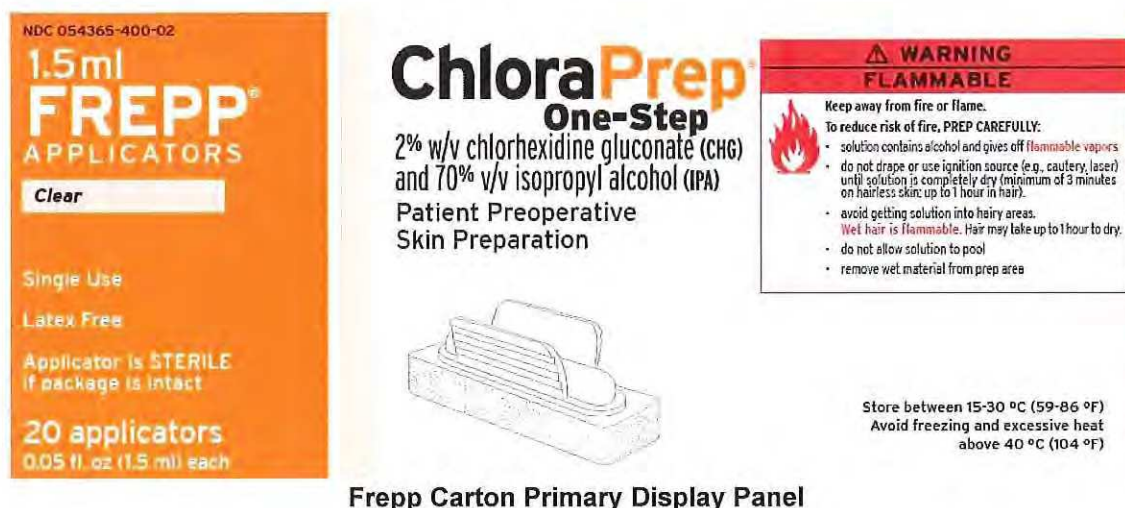
USP purified water

Questions?

www.chloraprep.com

call 1-800-523-0502 (M-F 8 a.m.-5 p.m. CST)

Package/Label Principal Display Panel



Frepp Carton Primary Display Panel

NDC 054365-400-02

1.5ml FREPP APPLICATOR

Clear

Single Use

Latex Free

Applicator is STERILE if packaging is intact

20 applicators

0.05 fl. oz. (1.5ml) each

Chloraprep® One-Step

2% w/v chlorhexidine gluconate (CHG) and 70% v/v isopropyl alcohol (IPA)

Patient Preoperative Skin Preparation

WARNING FLAMMABLE

Keep away from fire or flame.

To reduce risk of fire, PREP CAREFULLY:

solution contains alcohol and gives off **flammable vapors**

do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair).

avoid getting solution into hairy areas. **Wet hair is flammable.** Hair may take up to 1 hour to dry.

do not allow solution to pool

remove wet material from prep area

Store between 15-30 °C (59-86 °F)

Avoid freezing and excessive heat above 40 °C (104 °F)

Chloraprep One-Step			
chlorhexidine gluconate and isopropyl alcohol solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54365-400
Route of Administration	TOPICAL	DEA Schedule	
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength		Strength
CHLORHEXIDINE GLUCONATE (CHLORHEXIDINE)	CHLORHEXIDINE GLUCONATE		20 mg in 1 mL
ISOPROPYL ALCOHOL (ISOPROPYL ALCOHOL)	ISOPROPYL ALCOHOL		0.70 mL in 1 mL
Inactive Ingredients			
Ingredient Name	Strength		
WATER			
Packaging			
# Item Code	Package Description		
1 NDC:54365-400-02	20 POUCH (POUCH) in 1 CARTON		
1	1 APPLICATOR (APPLICATOR) in 1 POUCH		
1	1.5 mL in 1 APPLICATOR		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020832	04/26/2002	
Labeler - CareFusion 213 LLC (831684456)			
Establishment			

Name	Address	ID/FEI	Operations
CareFusion 213 LLC		830430810	ANALYSIS, MANUFACTURE

Revised: 05/2010

CareFusion 213 LLC

100% True Nascent Iodine

Sourced from deep within the
Earth Ultra powerful 1,950%
iodine



 Add to My Med List

More about Chloraprep One-Step (chlorhexidine topical)

- [Side Effects](#)
- [During Pregnancy or Breastfeeding](#)
- [Dosage Information](#)
- [0 Reviews - Add your own review/rating](#)

Professional resources

- [Chlorhexidine Gluconate topical](#) (AHFS Monograph)
- [Chlorhexidine Scrub](#) (FDA)
- *Other brands: [Peridex](#), [Periogard](#), [Betasept](#), [PerioChip](#), [More \(2\)](#) »*

Related treatment guides

- [Skin Disinfection, Preoperative](#)

DRUG STATUS



Availability
Rx and/or OTC



Pregnancy Category
Risk cannot be ruled out



CSA Schedule
Not a controlled drug



Drug Class

[Antiseptic and
germicides](#)

Related Drugs

[antiseptic and
germicides
Betadine, Peridex,
chlorhexidine
topical, Hibiclens,
iodine topical,
silver nitrate topical](#)

[Skin Disinfection,
Preoperative
chlorhexidine
topical, Hibiclens,
Betasept, Dyna-
Hex, Hibistat,
More...](#)

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ChloroPrep One-Step Rating

No Reviews - [Be the first.](#)

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EXHIBIT G3



We began by
saving lives on
the battlefield.

A photograph of military soldiers in camouflage gear in a desert environment. One soldier is lying on the ground, and others are attending to him. A helicopter is visible in the background.

We're bringing that
same life-saving
technology to

A photograph of surgeons in blue scrubs and masks performing surgery in an operating room. Medical monitors are visible in the background.



hospitals
worldwide.



One day we will advance
science-based infection
control technology.



One day we will create
products that enable
caregivers to reduce
hospital acquired
infections.



One day we will find a



way to effectively deliver
chlorhexidine where it's
needed most.

Today is that day.

When we started creating tactical combat care products for the United States Military Special Forces, our first priority was saving lives. Today, as entrotech life sciences defines and develops new areas of science-based infection control technology, our first priority remains unchanged – we exist to save lives.





entrotech life sciences.

Born on the battlefield.

We took on the toughest assignments. Vascular illumination. Manual respirators. Chest seals. The list goes on. In fact, there are seven entrotech life sciences products currently being utilized by Tier 1 fighters around the globe.

A photograph of a male scientist in a white lab coat looking through a microscope. The image is overlaid with a semi-transparent blue rectangle that serves as a background for the text.

The benefits of
Chlorhexidine
are well
documented.

It's the science
behind how it's
applied that is
revolutionary.

entrotech life sciences has pioneered a way to safely combine Chlorhexidine with polymers. This is the type of groundbreaking innovation that changes everything. Initially, it will enable caregivers to reduce hospital-acquired infections that cost thousands of lives and millions of dollars. Bigger picture, it has the capability to impact the spread of infections in any setting, not just healthcare institutions.

It's also the type of thinking people have come to expect from entrotech. Where our scientific background, advanced technology and intellectual capital give us the resources to solve the toughest problems.

See [entrotech](#) and [AERO](#) for additional background.



2,000,000

hospital acquired infections annually

80,000

lives lost

1

breakthrough solution



entrotech life sciences

CONTACT:

To learn more

about entrotech life sciences and our commitment to saving lives, contact:

Jim McGuire

CEO

entrotech life sciences

409 Illinois Street

San Francisco, California 94158

First and Last Name *

Company

Email *

Comments

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EXHIBIT G4



Off the shelf? Not here.

LEARN MORE ABOUT OUR SOLUTIONS



We manufacture original ideas.

If you want an off-the-shelf solution, sorry. And if you're looking for a link to our product catalog, there is no link. Because there is no catalog. But if you have something

you think can't be done. Bring it on. Because in this environment, where intellectual freedom and collaboration rule the day, anything is possible.



Ideas that effect real change.

We've eliminated the barriers to new thinking that exist in most companies. And as a result, we're generating solutions that are changing entire industries. But there is more to entrotech than innovative ideas. Our comprehensive capabilities include all aspects of product design and development – from initial research to state-of-the-art clean room manufacturing capabilities.

[STORY](#) [PEOPLE](#) [LOCATIONS](#) [SOLUTIONS](#) [NEWS](#) [CONTACT](#) [GOOGLE+](#)

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EXHIBIT G5

Overview

RELATED PRODUCTS

[ChloroPrep® 1 mL applicator](#)

[ChloroPrep® 3 mL applicator](#)

[ChloroPrep® 10.5 mL applicator](#)

[ChloroPrep® 26 mL applicator](#)

[ChloroPrep® Frepp® 1.5 mL applicator](#)

[ChloroPrep® Sepp® 0.67 mL applicator](#)

[ChloroPrep® swabstick](#)

RESOURCES

[Why skin preparation matters](#)

[The ChloroPrep® advantage](#)

[Using ChloroPrep®](#)

[ChloroPrep® in-service materials](#)

[ChloroPrep® mechanisms of action video](#)

[ChloroPrep® safety video](#)

[CMS Guidance on Alcohol-Based Skin Preparations in Anesthetizing Locations article](#)

DOWNLOADS

[ChloroPrep material safety data sheet](#)

ChloroPrep® FAQs

What is ChloroPrep patient preoperative skin preparation?

[What is ChloroPrep preoperative skin preparation?](#)

[What are the active ingredients of ChloroPrep patient preoperative skin preparation?](#)

[Is ChloroPrep preoperative skin preparation FDA approved?](#)

[How is receiving FDA approval for a NDA different than meeting the requirements of the FDA Tentative Final Monograph for Topical Antimicrobial Drug Products for Over-the-Counter Human use?](#)

[Which CDC guidelines recommend the use of a 2% chlorhexidine solution for skin antisepsis?](#)

[What category of CDC recommendation does 2% CHG receive?](#)

[Tell me about the ChloroPrep tints. Why are some applicators tinted, and are they safe?](#)

[In addition to CDC guidelines, are there other evidence-based guidelines that recommend the use of preoperative skin preparations containing chlorhexidine?](#)

Scientific and Clinical Support of 2% CHG and 70% IPA

[Why is the combination of 2% chlorhexidine gluconate \(CHG\) and 70% Isopropyl alcohol \(IPA\) better than IPA alone?](#)

[How does ChloroPrep patient preoperative skin preparation compare to traditional iodophors?](#)

[Does clinical data support the use of chlorhexidine to help reduce the incidence of infection?](#)

[Can ChloroPrep preoperative patient skin preparation help reduce the risk of blood culture contamination?](#)

[Can you explain the science of ChloroPrep preoperative skin preparation?](#)

ChloroPrep Applicators and Tints

[What makes ChloroPrep applicators unique?](#)

[What are the individual advantages of each ChloroPrep applicator?](#)

[How are the Scrub Teal and Hi-Lite Orange® tints removed from the skin?](#)

[What is the coverage area of each applicator?](#)

[What is the shelf life of ChloroPrep products?](#)

Using ChloroPrep Skin Antiseptic

[How do I know which applicator to use for a certain procedure?](#)

[How long does it take to prep a patient using ChloroPrep preoperative skin preparation? Is it less time than with other products?](#)

[Is ChloroPrep preoperative skin preparation safe to use with all procedures?](#)

[Why do the directions on the ChloroPrep preoperative skin preparation label indicate that it should be applied in a back-and-forth direction?](#)

[Request More Information](#)

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[Product support](#)

[ChloroPrep Label Update](#)

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Has ChloraPrep preoperative skin preparation been approved for use in small children?

Do studies support the use of ChloraPrep preoperative skin preparation in a surgical setting?

Customer Support

Can I get ChloraPrep preoperative skin preparation in a kit?

Are samples of ChloraPrep products available?

What is ChloraPrep preoperative skin preparation?

Q. What is ChloraPrep preoperative skin preparation?

A. ChloraPrep preoperative skin preparation is a rapid-acting and persistent preoperative skin preparation. Its proven formulation is available in six unique applicators designed for procedures ranging from peripheral IV insertion to major surgery.

[Top](#)

Q. What are the active ingredients of ChloraPrep preoperative skin preparation?

A. The active ingredients in ChloraPrep preoperative skin preparation are chlorhexidine gluconate (CHG) 2% w/v and isopropyl alcohol (IPA) 70% v/v.

[Top](#)

Q. Is ChloraPrep preoperative skin preparation FDA approved?

A. Yes. After submitting a New Drug Application (NDA) to the Food & Drug Administration, ChloraPrep preoperative skin preparation received FDA approval in 2000.

[Top](#)

Q. How is receiving FDA approval for a NDA different than meeting the requirements of the FDA Tentative Final Monograph for Topical Antimicrobial Drug Products for Over-the-Counter Human use?

A. When seeking FDA approval for an over-the-counter antiseptic, all manufacturers of chlorhexidine-based solutions are required to submit a New Drug Application (NDA). The review of a NDA by FDA includes evaluation of clinical, manufacturing and labeling information to assure the product is safe and effective.

Alcohol and iodophors were identified by FDA as "Generally Recognized As Safe and Effective" (GRASE) and are included in the Tentative Final Monograph from the FDA. As a result, manufacturers of alcohol, iodophors and iodine-based solutions can market products without submitting efficacy and safety data and product labeling to the FDA for review prior to marketing and selling their products.

[Top](#)

Q. Which CDC guidelines recommend the use of a 2% chlorhexidine solution for skin antisepsis?

A. ChloraPrep preoperative skin preparation meets the CDC's Guidelines for the Prevention of Intravascular Catheter-related Infections, published in 2002. The guidelines state that "clean skin with a >0.5% chlorhexidine preparation with alcohol before central venous catheter and peripheral arterial catheter."

[Top](#)

Q. What category of CDC recommendation does 2% CHG receive?

A. The use of a 2% chlorhexidine-based preparation for cutaneous antisepsis is classified as a Category 1A recommendation—the highest level of recommendation the CDC bestows. A Category 1A recommendation is clean skin with a >0.5% chlorhexidine preparation with alcohol before central venous catheter and peripheral arterial catheter."

[Top](#)

Q. Tell me about the ChloraPrep tints. Why are some applicators tinted, and are they safe?

A. The tint process for ChloraPrep Scrub Teal and Hi-Lite Orange® tints is a patented technology that adds color to the solution as it enters the sponge pad. When applied to the skin, each tint allows for easy visualization of the prepped area. Unlike iodine-based preps, which are brown, Scrub Teal and Hi-Lite Orange tints are easy to see when applied to a variety of skin tones.

The dyes in Scrub Teal and Hi-Lite Orange are Food, Drug and Cosmetic (FD&C) Green #3 and Yellow #6 dyes, and have been "Generally Recognized As Safe" (GRAS) by the Food and Drug Administration (FDA). For an ingredient to be listed as GRAS, extensive safety testing is conducted, reviewed and accepted. FD&C Green #3 is a common colorant used in many applications throughout the healthcare field (e.g., eye angiography and screening for ocular dryness, routine lab testing, dye injections, histological/cytological stains for cancer screening of tissues). FD&C Green #3 and Yellow #6 were found to be stable when combined with the 2% chlorhexidine gluconate/70% isopropyl alcohol ChloraPrep formulation, which offers proven, stable and uncompromised chlorhexidine-based solutions.

[Top](#)

Q. In addition to CDC guidelines, are there other evidence-based guidelines that recommend the use of preoperative skin preparations containing chlorhexidine?

A. Yes. Chlorhexidine gluconate is highly recommended by at least 18 organizations and initiatives, with 11 specifically advocating a 2% formulation. For a complete listing click [here](#).

[Top](#)

Scientific and Clinical Support of 2% CHG and 70% IPA

Q. Why is the combination of 2% chlorhexidine gluconate (CHG) and 70% isopropyl alcohol (IPA) better than IPA alone?

A. The combination of fast-acting and long-lasting antimicrobial activity is the key to an effective preoperative skin preparation. IPA alone provides a 99.99% reduction in bacteria, but it does not provide long-lasting microbial kill. CHG maintains antimicrobial activity, demonstrating 2 log₁₀ and 3 log₁₀ for at least 48 hours^{1,2} compared to two hours for free iodine.³ Because ChlorPrep preoperative skin preparation contains the combination of isopropyl alcohol and chlorhexidine, it is more effective than isopropyl alcohol alone.

[Top](#)

Q. How does ChlorPrep preoperative skin preparation compare to traditional iodophors?

A. Advantages of ChlorPrep preoperative skin preparation include its broad spectrum, rapid-acting and persistent antimicrobial activity (48 hours) and effectiveness in the presence of blood and organic matter. These advantages are a result of the unique 2% CHG/70% IPA formulation of ChlorPrep preoperative skin preparation. Chlorhexidine gluconate, a cationic bisbiguanide, works by destroying the bacterial cell membrane and precipitating cell contents. Alcohol denatures cell proteins. As a result, ChlorPrep preoperative skin preparation provides better broad spectrum, immediate, cumulative and residual antibacterial activity compared to traditional iodophors.

In contrast, traditional iodophors can take two to three minutes until the free release of iodine can occur. While the iodophor dries, free iodine becomes available. The iodine then attacks the bacterial cell and the oxidation of two sulfhydryl groups, resulting in the formation of a disulfide bond. The effectiveness of iodophors is ≤ three hours. Lastly, iodophors are neutralized in the presence of blood and organic matter and have greater irritation than the CHG solution.⁴

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Q. Does clinical data support the use of chlorhexidine to help reduce the incidence of infection?

A. Yes. Chlorhexidine-based antiseptics have been used globally for more than 50 years and have been widely used in Europe, Canada and Japan for more than 30 years. In the United States alone, more than 100 studies (excluding those focused on hygiene data) have been published, revealing positive outcomes related to the use of CHG-based antiseptics. Studies that used ChlorPrep preoperative skin preparation specifically, represent close to 25% of the published CHG data in the healthcare setting.

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Q. Can ChlorPrep preoperative skin preparation help reduce the risk of blood culture contamination?

A. Yes. A prospective blood culture study showed CHG was highly effective in reducing the contamination rate of blood cultures. The rate of blood culture contamination was lowered to 0.5% (1 of 215 cultures) with CHG.⁵ Another blood culture study found that tincture of iodine yielded a slightly higher contamination rate than chlorhexidine. In addition, iodine tincture has the disadvantage of being toxic when used repeatedly, while toxicity was found to be very uncommon with chlorhexidine.⁶

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Q. Can you explain the science of ChlorPrep preoperative skin preparation?

A. The chlorhexidine bisbiguanide groupings associate strongly to exposed anionic sites on the cell wall and cell membrane, particularly acidic phospholipids and proteins, causing displacement of divalent cations (Ca²⁺ and Mg²⁺). Bridging adjacent phospholipids in the cell membrane will cause a loss of structural integrity, reduce membrane fluidity and allow leakage of cellular materials.⁷

Bacterial cells are negatively charged, but in the presence of chlorhexidine, the bacterial cell is neutralized and the charge is reversed. The attraction of the cationic chlorhexidine molecule and the negatively-charged bacterial cell contributes to a rapid rate of bacterial kill; surface charge reversal is secondary to cell death.⁴

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ChlorPrep Applicators and Tints

Q. What makes ChlorPrep applicators unique?

A. ChlorPrep applicators have been designed as convenient single-use, latex-free, hands-off applicators. Designed for a smooth delivery of the appropriate amount of solution for each respective procedure, the packaging for the Swabstick and the patented glass ampule in the Sepp®, Frepp®, 3 mL, 10.5 mL and 26 mL applicators eliminate the risk of contaminated solution and protect the CHG molecule from degradation.

Furthermore, ChlorPrep Frepp, 3 mL, 10.5 mL and 26 mL applicators each use a patented "wing" design to minimize instances where aseptic technique is compromised.

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Q. What are the individual advantages of each ChlorPrep applicator?

A. Each ChlorPrep applicator offers a number of unique benefits to preoperative skin preparation. To learn more about the Sepp, Frepp, single and triple Swabstick, 3 mL, 10.5 mL and 26 mL applicators, visit the [Product Line Page](#).

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Q. How are the Scrub Teal and Hi-Lite Orange tints removed from the skin?

A. It is recommended that ChlorPrep preoperative skin preparation with tint remain on the skin, especially at the incision site, post-procedure to provide maximum antimicrobial activity. The tints will slowly fade from the skin. If your facility's policies or procedures

require cleanup and/or removal of the ChloraPrep tints, they can be removed with a ChloraPrep clear applicator, alcohol or soap and water.

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Q. What is the coverage area of each ChloraPrep applicator?

A. The coverage area is specific to each applicator. You can reference coverage area and the many other benefits of the full line of applicators at the ChloraPrep [Product Line Page](#).

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Q. What is the shelf life of ChloraPrep products?

A. The ChloraPrep single and triple Swabstick applicators have a two-year shelf life from the date of production. All other ChloraPrep products are labeled with a three-year shelf-life from the date of production.

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Using ChloraPrep preoperative skin preparation

Q. How do I know which applicator to use for a certain procedure?

A. Each ChloraPrep applicator is appropriate for a variety of procedures, depending on the size of the area that needs to be prepped. To review a list of common applicator procedures, go to the [Product Line Page](#).

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Q. How long does it take to prep a patient using ChloraPrep preoperative skin preparation? Is it less time than with other products?

A. Prepping time varies by the location and size of the prep site and applicator. Prepping with ChloraPrep preoperative skin preparation is a procedure that, compared to the "scrub and paint technique," greatly reduces the amount of time required for patient preoperative skin preparation.

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Q. Is ChloraPrep preoperative skin preparation safe to use with all procedures?

A. ChloraPrep preoperative skin preparation is for external use only.
Use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.
ChloraPrep should not be used:

On patients with known allergies to chlorhexidine gluconate or isopropyl alcohol

For lumbar puncture or in contact with the meninges

On open skin wounds or as a general skin cleanser

In or around eyes, ears, and mouth. May cause serious or permanent injury if permitted to enter and remain

Additional labeled warnings of ChloraPrep preoperative skin preparation include:

Solution contains alcohol and gives off flammable vapors—allow to dry three minutes on hairless skin.

Do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum of three minutes on hairless skin; up to 1 hour in hair).

Avoid getting solution into hairy areas, as wet hair is flammable; Hair may take up to 1 hour to dry. Reduced dry time for smaller applicators.

Do not allow the solution to pool.

Remove any soaked materials, drapes and gowns before using ignition sources.

Whenever prepping the neck area, place towels under each side to absorb excess solution and then remove.

For additional information on Prevention of Fire in the operating room please visit the following websites:

AORN Guidance Document: Fire Prevention in the Operating Room

NFPA accepts ASHE's amendment to NFPA 99 on Alcohol Based Surgical Prep Solutions

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Q. Why do the directions on the ChloraPrep preoperative skin preparation label indicate that it should be applied in a back-and-forth direction?

A. Clinical testing has shown that the back-and-forth motion used to apply ChloraPrep preoperative skin preparation supports the efficacy of the solution. Because 80% of transient skin flora resides in the first five cell layers of skin¹¹, it is important to reach those lower layers and kill the bacteria dwelling further down. The skin contains many cracks and crevices where harmful bacteria reside. The back-and-forth action creates friction and helps drive the solution into crevices and lower layers, reaching more bacteria. Further, there is no published data to support the concentric circular application methodology.

The New Drug Application (NDA) approved by the FDA for ChloraPrep preoperative skin preparation included in vivo studies that showed that a minimum 3 log₁₀ reduction for 48 hours was achieved on moist sites, and a 2 log₁₀ reduction for 24 hours was achieved on dry sites while using a friction (back-and-forth) scrub.

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Q. Has ChloraPrep preoperative skin preparation been approved for use in small children?

A. Use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.

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Q. Do studies support the use of ChloraPrep preoperative skin preparation in a surgical setting?

A. Yes. ChloraPrep preoperative skin preparation has been tested in a surgical setting measuring bacterial colonization reduction comparisons among preoperative skin preparations. Clinical outcomes concluded, ChloraPrep preoperative skin preparation was the most effective solution for eliminating potential wound contaminants from the forefoot prior to surgery.⁹

At the Invasive Heart Lab of Aultman Hospital in Canton, OH, ChloraPrep preoperative skin preparation was part of three evidence-based improvements put in place to reduce the risk of infections related to pacemakers and ICDs. These evidence-based improvements and focus on heart lab protocols yielded dramatic results. For 22 months, the intensive heart lab had no infections—a 0% infection rate. "By adhering to key evidence-based standards and protocols, we're protecting our patients from avoidable infections."—Beth A. Taylor RN, BC, CVNII¹⁰

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Customer Support

Q. Can I get ChloraPrep preoperative skin preparation in a kit?

A. Yes. The full line of ChloraPrep applicators is available in a wide range of kits and trays. Our trained Customer Support representatives can work with your facility kit manufacturers to include ChloraPrep preoperative skin preparation in your current SPT/CPT kits.

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Q. Are samples of ChloraPrep products available?

A. Yes. Samples of all our ChloraPrep applicators are available. To request samples please contact ChloraPrep Customer Support at 800.523.0502 ext. 3576.

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EXHIBIT G6



CareFusion Brands

At CareFusion, we are united in our vision to improve the safety and cost of healthcare for generations to come. We are passionate about healthcare and helping those who deliver it—from the hospital pharmacy to the nursing floor, the operating room to the patient bedside. Our family of products and services are used in more than 130 countries and include some of the most widely recognized brand names in their categories. Through these brands, the 16,650 employees of CareFusion are dedicated to making global healthcare better for generations to come.

Infection Prevention

ChloraPrep®
ChloraShield®
MaxGuard®
MaxPlus®
MedMined®
CareFusion SmartWorks

Medication Management

Alaris®
Guardrails®
MedMined®
MedSystem III®
Pyxis®
Rowa
SmartSite®
CareFusion SmartWorks
Texium®

OR Effectiveness

AVAmox®
MedMined®
PleurX®
Pyxis®
CareFusion SmartWorks
Snowden-Pencer®
V. Mueller®
Vital Signs®

Respiratory Care

AirLife®
Bird®
Jaeger®
CareFusion SmartWorks
Tiara
Viasys®
Vital Signs®
Vmax™

EXHIBIT G7

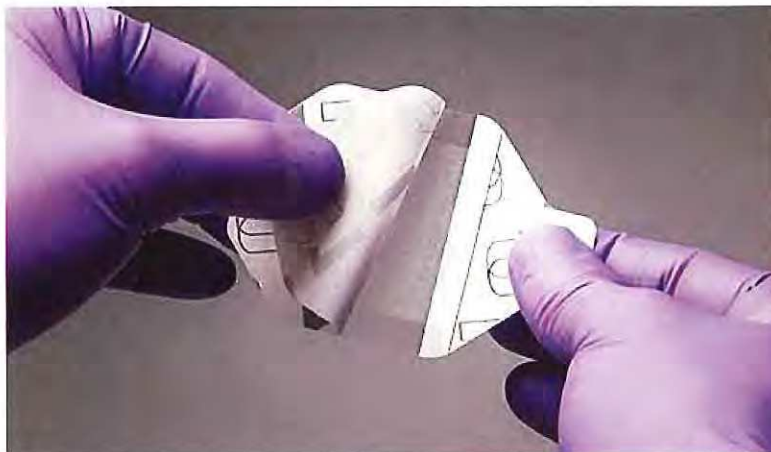
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ChloraShield® IV dressing

Protect and preserve IV access sites with an innovative adhesive technology that preserves the dressing

The ChloraShield® IV dressing with chlorhexidine gluconate (CHG) antimicrobial was designed with the patient and clinician in mind. For patients, the dressing is flexible and breathable, providing comfort during wear. For clinicians, the adhesive has CHG incorporated, and the dressing is designed to deliver optimized fluid management, protecting the site and enhancing patient care.

Product highlights



BeneHold™ CHG adhesive technology by Vancive Medical Technologies™

- Offers thin, strong adhesive to secure the dressing to the skin for up to seven days¹
- CHG within the adhesive preserves the dressing from microbial growth²
- Proprietary formulation that can wick away and absorb fluid³



Transparent film with CHG incorporated over a large area of the adhesive

- Allows site visibility and becomes fully transparent for ongoing inspection
- Allows vapor exchange and release of absorbed fluid³
- Provides a barrier to external contaminants including fluids, bacteria, viruses* and yeast⁴

Built in data strip

- Facilitates documentation pre or post application



- Eliminates an extra application step
- Denotes the dressing contains CHG



Manufactured by:
Avery Dennison België BVBA
Tieblokkenlaan 1, B-2300 Turnhout, Belgium

1. Wear test study on healthy human S13-19
 2. Bacteria time kill study R31476-R0
 3. Report aw\31012014-1
 4. Viral penetration test ASTM F-1671
- * From viruses 27 nm in diameter or larger

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CERTIFICATE OF SERVICE

I hereby certify that, on this 21st day of May, 2015, a true and correct copy of **APPLICANT'S NOTICE OF RELIANCE** has been served by electronic mail upon Opposer's attorneys of record in this proceeding at the following electronic addresses:

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